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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,208	02/05/2004	Roland Buelow	39691-0002A	6944

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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,208	BUELOW ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-28 are pending in the present application, and they are subjected to the following election/restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction

I. Claims 1-15 and 24, drawn to a method for producing humanized or human antibodies comprising the step of treating a transgenic non-human animal in which rearrangement of immunoglobulin genes substantially stops early in life, engineered to express one or more humanized or human immunoglobulin loci, with at least one antibody specific for the endogenous surface IgM and/or IgD heavy and/or light chains produced by early B cells in said animal, classified at least in class 424, subclass 130.1.

II. Claims 16-23 and 25-28, drawn to a method for suppressing endogenous immunoglobulin expression in a non-human animal comprising expressing in said animal one or more transgenes encoding one or more antibodies specific for the endogenous surface IgM and/or IgD heavy and/or light chains produced by early B cells of said non-human animal; a method for producing a non-human transgenic animal in which endogenous immunoglobulin production is suppressed; and a non-human transgenic

animal dominantly expressing human or humanized antibodies, classified in class 800, subclasses 13, 21.

The above inventions are distinct, each from the others because of the following reasons:

The methods in Groups I-II are drawn to distinct methods having different method steps and starting materials one from the other, and therefore they would require different technical considerations for achieving the desired end results. For example, the method of Group I does not involve the expression in a non-human animal one or more transgenes encoding one or more antibodies specific for the endogenous surface IgM and/or IgD heavy and/or light chains as required by the method of Group II, but rather treating a non-human animal with at least one antibody specific for the endogenous surface IgM and/or IgD heavy and/or light chains.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements in both patent and non-patent literature searches due to the distinctness of the inventions as set forth above, it would be unduly burdensome for the examiner **to search and/or consider the patentability of all the inventions** in a single application, restriction for examination purpose as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Species Restriction

I. Should Applicants elect Group I, this application contains claims directed to the following patentably distinct species of treating an animal with an antibody in the claimed invention:

(a) an antibody specific for the endogenous surface IgM heavy chain; (b) an antibody specific for the endogenous surface IgM light chain; (c) an antibody specific for the endogenous IgD heavy chain; (d) an antibody specific for the endogenous IgD light chain; or (e) a specific combination of the antibody in (a)-(d).

The species are independent or distinct because each treatment involves distinct antibodies that are different structurally and property one from the others, e.g., whether the antibody recognizes IgM heavy chain or IgM light chain or IgD heavy chain or IgD light chain and so forth.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1-15 and 24 are generic.

Additionally, this application contains claims directed to the following patentably distinct species of an antibody in the claimed invention:

(a) a polyclonal antibody; (b) a monoclonal antibody.

The species are independent or distinct because a polyclonal antibody is distinct structurally and it has different properties from a monoclonal antibody.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1-6, 15 and 24 are generic.

Furthermore, this application contains claims directed to the following patentably distinct species of a transgenic non-human animal in the claimed invention:

A single specific animal recited in the Markush group of claim 4.

The species are independent or distinct because each animal is distinct one from the others structurally. A rabbit is distinct from a cow, a bird, a pig or a horse.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1-6, 15 and 24 are generic.

II. Should Applicants elect Group II, this application contains claims directed to the following patentably distinct species of expressing in a non-human animal one or more transgenes encoding for one or more antibodies in the claimed invention:

(a) an encoded antibody specific for the endogenous surface IgM heavy chain; (b) an encoded antibody specific for the endogenous surface IgM light chain; (c) an encoded antibody specific for the endogenous IgD heavy chain; (d) an encoded antibody specific for the endogenous IgD light chain; or (e) a specific combination of the encoded antibody in (a)-(d).

The species are independent or distinct because each expression step involves distinct one or more transgenes encoding one or more distinct antibodies that are different structurally and property one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 16-23 and 25-28 are generic.

Additionally, this application contains claims directed to the following patentably distinct species of a non-human animal in the claimed invention:

A single specific animal recited in the Markush group of either claim 22 or claim 28.

The species are independent or distinct because each animal is distinct one from the others structurally. A rabbit is distinct from a cow, a bird, a pig or a horse.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 16-23 and 25-28 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Dave Nguyen, may be reached at (571) 272-0731.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

QUANG NGUYEN, PH.D
PATENT EXAMINER